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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Baudry Jacquet

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YOUNG & THOMPSON
209 Madison Street
Suite 500
Alexandria, VA 22314

EXAMINER

DAVIS, DEBORAH A

ART UNIT

PAPER NUMBER

1655

NOTIFICATION DATE

DELIVERY MODE

08/23/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summary	Application No. 10/578,089	Applicant(s) JACQUET, BAUDRY	
	Examiner DEBORAH A. DAVIS	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9 and 11-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9 and 11-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' amendment filed 6-22-10 has been received and entered. Currently, claims 9 and 11-25 are pending and under consideration for examination.

Claim Objections

Claim 16 stand objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim for reasons of record and restated below:

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 16 requires that composition (a) be administered in the first part of the day and composition (b) be administered in the second part of the day. These limitations do not further limit the parent claim 9 that requires that composition (a) be administered separately and consecutively.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9 and 11-25 stand rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling for reasons of record and restated below:

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The table below includes compositions (a) and (b) that has been demonstrated in the instant specification as critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Further, the specification demonstrates a method for treating cosmetic skin conditions as it relates to dry skin and wrinkles but not enabled for any and all skin conditions.

Borage oil	357mg
Green tea extract	200mg
Calcium ascorbate (vitamin C)	75mg
Natural beta carotene (vitamin A)	2.4mg
Lecithin	13.6mg
Yellow beeswax	10.8mg
Chromium chloride	0.06mg
Zinc sulphate	13.7mg
Sodium selenate	0.05mg
Capsule shell	Fish gelatine, glycerine, water and food colouring

Concentrated fish oil	365mg
Grape-cake extract	150mg
Shark cartilage	100mg
Iron fumarate	31.8mg
Copper sulphate	2.6mg
Yellow beeswax	15mg
Vitamin B2 (Riboflavin)	1.6mg
Vitamin B5 (calcium pantothenate)	6.55mg
Vitamin B6 (pyridoxine chlorhydrate)	2.4mg
Vitamin B8 (biotin)	0.15mg
Lecithin	12mg
Capsule shell	Fish gelatine, glycerine, water and food colouring

The inclusion of essential elements in the method comprising the compositions administered in effective amounts for treating conditions of the skin, hair, nails and/or for treating overweight conditions of a human in need thereof. (see specification, pages 12-16, e.g.).

The factors regarding undue experimentation have been summarized in *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Circ. 1988) as follows:

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- (1) The quantity of experimentation necessary (time and expense);
- (2) The amount of direction or guidance presented;
- (3) The presence or absence of working examples of the invention;
- (4) The nature of the invention;
- (5) The State of the prior art;
- (6) The predictability or unpredictability of the art;
- (7) The breadth of the claims; and
- (8) The relative skill of those in the art

All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the invention: The instantly claimed invention is drawn to a method for treating conditions of the skin, hair, nails and/or overweight conditions of a human in need thereof, comprising orally administering to said human a combination product comprising: a first composition (a) containing a green tea extract, vitamin C, and optionally at least one metallic compound selected from zinc, chromium and a mixture thereof, and a second composition (b) containing at least one metallic compound selected from iron, copper, chromium and a mixture thereof. The compositions (a) and (b) are separately and consecutively orally administered to said human, wherein zinc and iron are not simultaneously present in the same composition.

Breadth of the claims: The claims were given its broadest and reasonable interpretation that is consistent with applicant's specification.

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State of the art: The prior art demonstrates the claimed composition to work in canine dogs and pets, not people, as claimed. For example, the reference of Rapisarda (US 6,974,841) beneficially teaches nutritional supplement for pets that comprise of green tea, vitamin C, chromium and zinc. Two tablets of the supplements are administered in the morning to pets, which would read on consecutive administration of two compositions not having iron and zinc together in the same composition. The composition is designed to improve wellness and to fight anti-aging effects (see abstract and column 2, e.g.).

Guidance of the Specification and Existence of Working Examples:

Please see compositions (a) and (b) in the above described tables. The example compositions (a) and (b) above were administered to volunteers for treating hair loss, wrinkles of the skin, and breakage of nails in an amount of two capsules of composition (a) in the morning and 1 capsule of composition (b) in the evening for two months. The results observed were reduced hair loss, reduction in wrinkles and improvements in dry skin and nail solidity (specification, pages 14-19, e.g.). The composition that is instantly claimed has not demonstrated that when administered will treat conditions of hair, skin, and nails and/or weight loss. Although the M.P.E.P does not require the applicant to provide examples, however, there must be sufficient teaching in the absent of examples in the specification to enable one of ordinary skill in the art at the time the invention was made to make the invention commensurate in scope with the claims.

Amount of Experimentation Necessary: The instant claims only include as active ingredients a first composition (a) containing a green tea extract, vitamin C, and

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optionally at least one metallic compound selected from zinc, chromium and a mixture thereof; and, a second composition (b) containing at least one metallic compound selected from iron, copper, chromium and a mixture thereof. The claimed composition is distinct as compared to what is demonstrated in applicant's specification. The quantity of experimentation necessary to carry out the claimed invention is high, as the skilled artisan could not rely on the instant claims as drafted comprising a method for treating conditions of the skin, hair, nails and/or overweight conditions of a human in need thereof because there is not a sufficient teaching or examples that would lead one of ordinary skill in the art to use the claimed composition with an expectation of success.

The office does not have the facilities for examining and comparing applicant's claimed product with the product that is demonstrated to work. In the absence of evidence to the contrary, the burden is upon the applicant.

Response to Arguments

Applicant's arguments filed 6-22-10 have been fully considered but they are not persuasive of error.

Applicant argues that the objection of claim 16 is improper because it depends from claim 1 which recites that the composition is administered separately and consecutively. This argument have been fully considered but not found to be persuasive of error.

In response, the composition of claim 16 is administered separately but not consecutively. The composition of claim 16 is administered once in the morning and

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then the evening which is separately but not consecutively. Consecutive administration would be to administer composition (b) right after the administration of composition (a). Therefore this objection is maintain and made final.

Applicant argues that the claims are enabled because they have been amended to include the critical or essential compositions that were not previously included. Applicant directs the examiner's attention to page 3, lines 8-17 in the specification for support. Applicant also provides Examples I and 3 as further support of the claims being enabled. Applicant argues that green tea extract, vitamin C, chromium chloride and zinc sulphate in composition (a) and iron fumarate and copper sulphate in composition (b) are the active ingredients that is effective for the method of treating skin, hair, nails, and/or overweight conditions. These arguments have been fully considered but not found to be persuasive of error.

In response, the support that applicant refers to is a general statement that states the combination of green tea extract, vitamin C and metallic compounds selected from zinc, chromium, iron, and copper exerted action on skin, hair, nails and weight. Applicant has not demonstrated through sufficient teaching or example that the claimed composition is enabled. Although the M.P.E.P does not require applicant to provide examples, however there must be a sufficient teaching and not just generalized statements of how to use the composition in commensurate with the scope of the claims. With respect to Example 1, applicant argues that composition (a) comprises of green tea extract, vitamin C, chromium chloride and zinc sulphate. Composition (b)

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comprise of iron fumarate and copper sulphate. However, applicant neglected to mention the additional ingredients of Borage oil, and Natural beta carotene in composition (a) and Grape extract, and fish oil in composition (b) as effective ingredients included in the treatment when administered to volunteers (see specification, page 14, e.g.). This is also the case for Example 3 as well; the additional ingredients of Natural beta carotene (800mg) and Borage oil (700mg) in composition (a) and Grape extract (150mg) and Shark cartilage (100mg) in composition (b) were administered to volunteers for the treatment of hair, nails, skin and weight. There is no teaching or suggestion that the additional ingredients in compositions (a) and (b) of Examples 1 and 3 are not critical. The examiner can only look to the teaching of the specification and the prior art as guidance for enablement. Thus, there is no suggestion or teaching in the specification or the prior art that would enable one of ordinary skill in the art that absent the additional ingredients in Examples 1 and 3 would be effective to treat conditions of the skin, hair, nails and weight conditions. Therefore, this rejection is maintained and made final.

Conclusion

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEBORAH A. DAVIS whose telephone number is (571)272-0818. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Deborah A. Davis
Patent Examiner, AU 1655
August 2010

/Christopher R. Tate/
Primary Examiner, Art Unit 1655